II. Remarks

A. Status of the Claims

Claims 13-24 and 57 will be currently pending after entry of this amendment. Claims 1-12 and 25-56 were previously cancelled. Claim 13 has been amended without prejudice. New claim 57 has been added. Support for the amendments to claim 1 can be found throughout the original application as filed, e.g., at paragraphs [0021] and [0079]. Support for new claim 57 can be found, e.g., at paragraph [00101]. Applicants respectfully submit that no new matter has been added by virtue of this amendment.

B. Summary of Interview

Applicants wish to thank Examiner Westerberg and Examiner Jones for the courtesies extended in the February 21, 2008 Interview with Applicants' representatives. During the interview, issues in formulating baclofen were discussed and how it has been addressed in the prior art. Also discussed was the proposed amendment to claim 1 (filed herewith) which the Examiners stated appears to overcome the rejections over Sunshine et al.

Baclofen Administration

Applicant's representatives discussed with the Examiners that baclofen absorption in the gastrointestinal tract is site specific. Baclofen is primarily absorbed in the upper gastrointestinal tract, with the extent of absorption of baclofen substantially reduced in the lower gastrointestinal tract (see paragraph [0004] of the instant specification).

In attempts to provide baclofen dosage forms, the prior art has, e.g., formulated baclofen as oral bioadhesive tablets or as gastroretentive dosage forms to avoid or substantially avoid release of baclofen from the formulation in the lower gastrointestinal tract.

Rejection under 35 U.S.C. § 112, second paragraph

During the Interview, Applicants' representatives discussed the claim rejections under 35 U.S.C. § 112, second paragraph as it was applied to the recited ratio of "1:10 to about 10:1". Applicants' representatives explained that the claimed ratio is with respect to the entire component, rather than directed solely to the active agent. Applicants' representatives stated that support for this position is by the recitation of the ratio itself, which states the "ratio of said immediate release component to said controlled release component". The Examiners appeared to agree with this position and requested a statement for the record in the response.

The Sunshine et al. Reference

In the Office Action, the Examiner stated that "[t]he teachings of Sunshine et al. as to the use of equal amounts of skeletal muscle relaxants in a composition having both an immediate and sustained release component renders obvious to one of ordinary skill in the art..."

During the interview, the Applicants' representatives discussed that none of the formulations with a sustained release and immediate release component in Table IV at column 15 of Sunshine et al. include baclofen. It was also discussed that baclofen is not equivalent to skeletal muscle relaxants that are included in the Table IV formulations, as evidenced by Sunshine et al. at column 12, which categorizes baclofen as a "miscellaneous" chemical group.

During the interview, the Examiners were directed to column 17, lines 53-64 of Sunshine et al. which generally discusses that the compositions described therein can be formulated in sustained release form, but does not specifically discuss baclofen or any particular ingredients to utilize in formulating baclofen. Further, the Examples of Sunshine et al. are directed to what appear to be immediate release dosage forms and therefore do not provide any further guidance to the discussion at column 17.

It was further discussed that Sunshine et al. does not recognize the issue that the extent of absorption of baclofen is substantially reduced in the lower gastrointestinal tract.

In order to further differentiate Sunshine et al., Applicants' representatives discussed amending the claims to include (i) specific materials that can be utilized as controlled release components and (ii) the limitation that the dosage form releases at least 25% $GABA_B$ agonist in the intestinal tract.

As indicated in the Interview Summary, the Examiners indicated that these amendments appear to overcome the Sunshine et al. rejection. The Examiners further indicated that it the proposed amendments appear to overcome the further rejections utilizing Sunshine et al.

C. Claim Rejections Under 35 U.S.C. § 112

In the Office Action, claims 13-17, 20, 21, 23 and 24 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite, specifically for the phrase "wherein the ratio of said immediate release component to said controlled release component is from about 1:10 to about 10:1", because "[n]o indication is given in the claims as to what information is used to calculate the ratio."

In response, as explained to the Examiners during the February 21, 2008 Interview, Applicants respectfully point out that the ratio is calculated based on the amount of immediate release component to the controlled release component. As discussed during the interview, Applicants submit that support for this position is by the recitation of the ratio itself, which states the "ratio of said immediate release component to said controlled release component".

Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 112, second paragraph be removed.

C. Claim Rejections Under 35 U.S.C. § 103(a)

1. Sunshine et al.

In the Office Action, claims 13-16, 20, 21 and 23 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,780,463 to Sunshine et al.

As discussed during the interview, Applicants respectfully submit that in view of Sunshine et al., one skilled in the art would not be motivated to prepare a $GABA_B$ agonist formulation that, at the very least, (i) includes a controlled release component that incorporates the specific material(s) presently recited in the claims and (ii) releases at least 25% $GABA_B$ agonist in the intestinal tract.

The Examiners stated that the present claims appear to overcome Sunshine et al. and Applicants respectfully request that the rejection under 35 U.S.C. § 103(a) over Sunshine et al. be removed.

2. Sunshine et al. in view of Fara et al.

In the Office Action, claim 17 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Sunshine et al. in view of U.S. Publication No. 2003/0031711 to Fara et al.

As discussed during the interview, Fara et al. does not cure the deficiencies of Sunshine et al. as discussed above.

Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 103(a) over Sunshine et al. in view of Fara et al. be removed.

3. Sunshine et al. in view of Patel et al.

In the Office Action, claim 24 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Sunshine et al. in view of U.S. Patent No. 6,248,363 to Patel et al.

As discussed during the interview, Patel et al. does not cure the deficiencies of Sunshine et al. as discussed above.

Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 103(a) over Sunshine et al. in view of Patel et al. be removed.

III. Conclusion

In view of the amendments made and arguments presented, it is believed that all claims are in condition for allowance. If the Examiner believes that issues may be resolved by a telephone interview, the Examiner is invited to telephone the undersigned at (973)597-2404. The undersigned also may be contacted via e-mail at rparadiso@lowenstein.com. All correspondence should be directed to our address listed below.

AUTHORIZATION

The Commissioner is hereby authorized to charge any fees that may be required, or credit any overpayment, to Deposit Account No. 50-1358.

Respectfully submitted,
Lowenstein Sandler PC

Date: March 7, 2008

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